

CLAIMS

1. An immune modulator composition comprising a whole cell of a bacterium from the genera *Rhodococcus*, *Gordonia*, *Nocardia*, *Dietzia*, *Tsukamurella* and *Nocardioides*, wherein said immune modulator composition in use modifies a cellular
5 immune response.
2. An immune modulator composition according to claim 1 wherein said composition comprises an antigen and an adjuvant, wherein said adjuvant comprises a whole cell of a bacterium from the genera *Rhodococcus*, *Gordonia*, *Nocardia*, *Dietzia*,
10 *Tsukamurella* and *Nocardioides*.
3. A pharmaceutical composition comprising a whole cell of a bacterium from the genera *Rhodococcus*, *Gordonia*, *Nocardia*, *Dietzia*, *Tsukamurella* and *Nocardioides* and optionally a pharmaceutically acceptable carrier, diluent or excipient, which
15 pharmaceutical composition in use modifies a cellular immune response.
4. Use of an immune modulator composition or a pharmaceutical composition according to any one of claims 1 to 3 in the manufacture of a medicament for the treatment or prevention of one or more of an infection (e.g. a bacterial infection, a
20 viral infection for example an infection caused by papilloma viruses, including equine sarcoid, genital warts and dysplasia of the uterine cervix that precedes carcinoma of the cervix, or parasitic infection, for example, malaria, trypanosomiasis, leishmaniasis and toxoplasmosis) and/or the immunological abnormalities accompanying an infection, stress, for example, major trauma stress, psychosocial stress and chronic
25 stress, an allergy (e.g. asthma including allergic asthma, hayfever, allergic dermatitis (eczema), anaphylactic shock, allergies to plant contact or ingestion, stings – such as nettle and insect stings, and allergies to insect bites – such as midges, for instance *Culicoides* (which causes Sweet Itch in horses)), heaves, COPD and cancer (for example melanoma or adenocarcinoma or virally related cancer such as cervical
30 cancer); an immune system imbalance (e.g. an immune system imbalance in children and the elderly); and post-operative stress and post-operative infection.

5. Use of an immune modulator composition or a pharmaceutical composition according to any one of claims 1 to 3 in the manufacture of a medicament for the treatment or prevention of one or more of an infection, stress, an allergy, heaves, COPD, cancer and an immune system imbalance.
6. Use of an immune modulator composition or a pharmaceutical composition according to any one of claims 1 to 3 in the manufacture of a medicament for the treatment or prevention of an adverse reaction to childhood vaccines and/or consequences thereof.
7. Use of an immune modulator composition or a pharmaceutical composition according to any one of claims 1 to 3 in the manufacture of a medicament for modifying a cellular immune response.
8. An immune modulator composition or a pharmaceutical composition according to any one of claims 1 to 3 for use as a medicament.
9. An immune modulator composition or a pharmaceutical composition according to any one of claims 1 to 3 for use in or as a vaccine.
10. An immune modulator composition according to claim 9 wherein said vaccine is a prophylactic vaccine or a therapeutic vaccine.
11. An immune modulator composition according to claim 9 or claim 10 wherein said composition modifies a cellular immune response.
12. An immune modulator composition and/or a pharmaceutical composition according to any one of the preceding claims wherein said composition further comprises an antigen or antigenic determinant.

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13. An immune modulator composition and/or a pharmaceutical composition according to claim 12 wherein said antigen or antigenic determinant is an antigen or antigenic determinant selected from one or more of a BCG (bacillus of Calmette and Guerin) vaccine, a diphtheria toxoid vaccine, a diphtheria/tetanus/pertussis vaccine, a pertussis vaccine, the tetanus toxoid vaccine, the measles vaccine, the mumps vaccine, the rubella vaccine, the OPV (oral poliomyelitis vaccine) and *Mycobacterium vaccae*, or part thereof.
14. An immune modulator composition and/or pharmaceutical composition according to claim 12 or claim 13 wherein said composition comprises two or more such antigens or antigenic determinants.
15. An immune modulator composition and/or pharmaceutical composition according to any one of claims 1-3 and 8-14 wherein said bacterium is selected from the genus *Rhodococcus*.
16. An immune modulator composition and/or pharmaceutical composition according to claim 15 wherein said bacterium is one or more of the following *Rhodococcus ruber*, *Rhodococcus rhodococcus*, *Rhodococcus rhodnii*, *Rhodococcus coprophilus*, *Rhodococcus opacus* and *Rhodococcus erythropolis*.
17. An immune modulator composition and/or pharmaceutical composition according to any one of claims 1-3 and 8-16 wherein said bacterium is killed.
18. A method for treating or preventing a condition in a subject comprising administering an effective amount of a pharmaceutical composition and/or immune modulator composition according to any one of claims 1-3 and 8-17 to a subject wherein said composition modulates a cellular immune response.

19. A method for immunising a subject comprising administering a pharmaceutical composition and/or immune modulator composition according to any one of claim 1-3 and 8-17.
- 5 20. A method according to claim 18 or claim 19 wherein said pharmaceutical composition and/or an immune modulator composition is co-administered with an antigen or antigenic determinant.
- 10 21. A method according to claim 20 wherein the antigen or antigenic determinant is an antigen or antigenic determinant selected from one or more of a BCG (bacillus of Calmette and Guerin) vaccine, a diphtheria toxoid vaccine, a diphtheria/tetanus/pertussis vaccine, a pertussis vaccine, a tetanus toxoid vaccine, a measles vaccine, a mumps vaccine, a rubella vaccine, a OPV (oral poliomyelitis vaccine) and *Mycobacterium vaccae*, or part thereof.
- 15 22. A method according to claim 20 or claim 21 wherein said pharmaceutical composition and/or an immune modulator composition is co-administered with two or more such antigens or antigenic determinants.

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